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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/812,618

03/30/2004

Sunil Dhuper

2311

7278

7590

11/13/2007

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EXAMINER

MITCHELL, TEENA KAY

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

11/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/812,618		DHUPER ET AL.	
	Examiner		Art Unit	
	Teena Mitchell		3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/27/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 1792a. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because Fig. 1B there are listed numbers almost not readable appear to be 42b and 44; also in Fig. 1C (35c, 36c, 37c, 16c, 17c, 18c, 24c, 43c, 47c-49c, 7c-9c, 44c-46c (examples of)) all pointing to one element however in the specification the numerals are listed as different elements, this is also in Figs. 1D-1F, 2A-2F. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of

an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.84(h)(5) because Figures 2A-2F the figures are suppose to depict the bag being replaced by the tubing, however the bag is present in all the figures show(s) modified forms of construction in the same view. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

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drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because it is longer than 150 words. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities:

Page 18, line 13, "...ed..." should be amended to read --end--.

Page 19, line 2, "...camber..." should be amended to read --chamber--.

Page 24, line 16, "...ed..." should be amended to read --end--.

Correction is required.

Claim Objections

Claims 7 and 8 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claims 2-5 are objected to because of the following informalities: in claims 2-5, line 1; "...one..." should be amended to --1-- in order to be consistent with claims 6-8. In claims 3-5, MDI while such is a known abbreviation for

metered dose inhalator applicant should for the first recitation should list what is meant by MDI. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is unclear as to what is being claimed first there is a first housing or a fixed housing or a partially fixed and a partially collapsible/expandable first housing, then applicant claims a first housing that is fully collapsible, however if you have the first limitations of **or** how can you now claim the housing is now fully collapsible, thereby making the claim indefinite.

In claim 2, applicant claims a collapsible/expandable first and/or second housing then further on in the claims "...said housing..." it is unclear as to which housing applicant is making reference either the first or the second housing throughout the claims, thereby making the claim indefinite, clarification is requested.

In claim 3, which depends from claim 1, which claims a first and second housing and now in claim 3 another housing is being claimed, "...said housing..." is indefinite because it is unclear as to which housing applicant is making reference the first or second housing of claim 1 or the additional housing of claim 3.

In claim 3, applicant refers back to, "...corrugated tubing as described in claim 2..." while applicant defines tubing in claim 2 there is no mention in claim 2 that such tubing is corrugated.

Regarding claim 8, ".... the housing..." is indefinite, it unclear as to which housing applicant is making reference because claim 8 depends from claim 1 and 7, which has a first and second housing already being claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

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and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over King (5,848,587) the claims as best understood by the examiner.

Regarding claim 1, King discloses a fixed first housing with a configuration of a cylinder (note illustration of Fig. 2 below), a fixed second housing; the first housing that is connected to the second housing through one of more peripheral and/or central hollow connecting tubes (note illustration of Fig. 2 below); the first housing with an inhalation/exhalation outlet tube at an inhalation/exhalation end of the first housing (Fig. 2 below); the inhalation/exhalation outlet tube with an inhalation/exhalation outlet port at the end of the inhalation/exhalation outlet tube (Fig. 2 below); the first housing with an inlet tube at a diametrically opposite end of the inhalation/exhalation outlet tube (Figs. 2 below); the inlet tube with an inlet port at an end of the inlet tube (Fig. 2 below); a boot adapter panel (Figs. 2 below) with an opening for receiving a boot of an MDI inhaler; a one-way inhalation flap valve assembly (at 64) that comprises an inhalation flap valve (at 64b), and a valve seat (64a) for the inhalation flap valve that is disposed in the outlet port of the outlet tubing of the first housing; the one way valve assembly (at 64) whereby inhalation by a patient through the inhalation/exhalation outlet port will cause the inhalation flap valve to move away from the inhalation flap valve

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seat (64a) to allow one way flow of gas(es) from the first housing to a mouth piece or a face mask (Col. 3, lines 52-59) through the inhalation/exhalation outlet port of the first housing presses the inhalation flap against the inhalation flap valve seat (64a) to prevent the flow of exhaled gas into the first housing; a one way exhalation flap valve assembly (at 62), the difference between King and claim 1 is the exhalation flap valve seat. King discloses a ball check valve in the exhalation flap assembly, which does have a valve seat however not the same seat as the flap valve of the inhalation valve, inasmuch as the inhalation type flap valve as well known it would have been obvious to one of ordinary skill in the art to substitute the ball check valve in the exhalation pathway to the valve assembly of the inhalation pathway as one well known valve means for another. King discloses an exhalation filter (14).

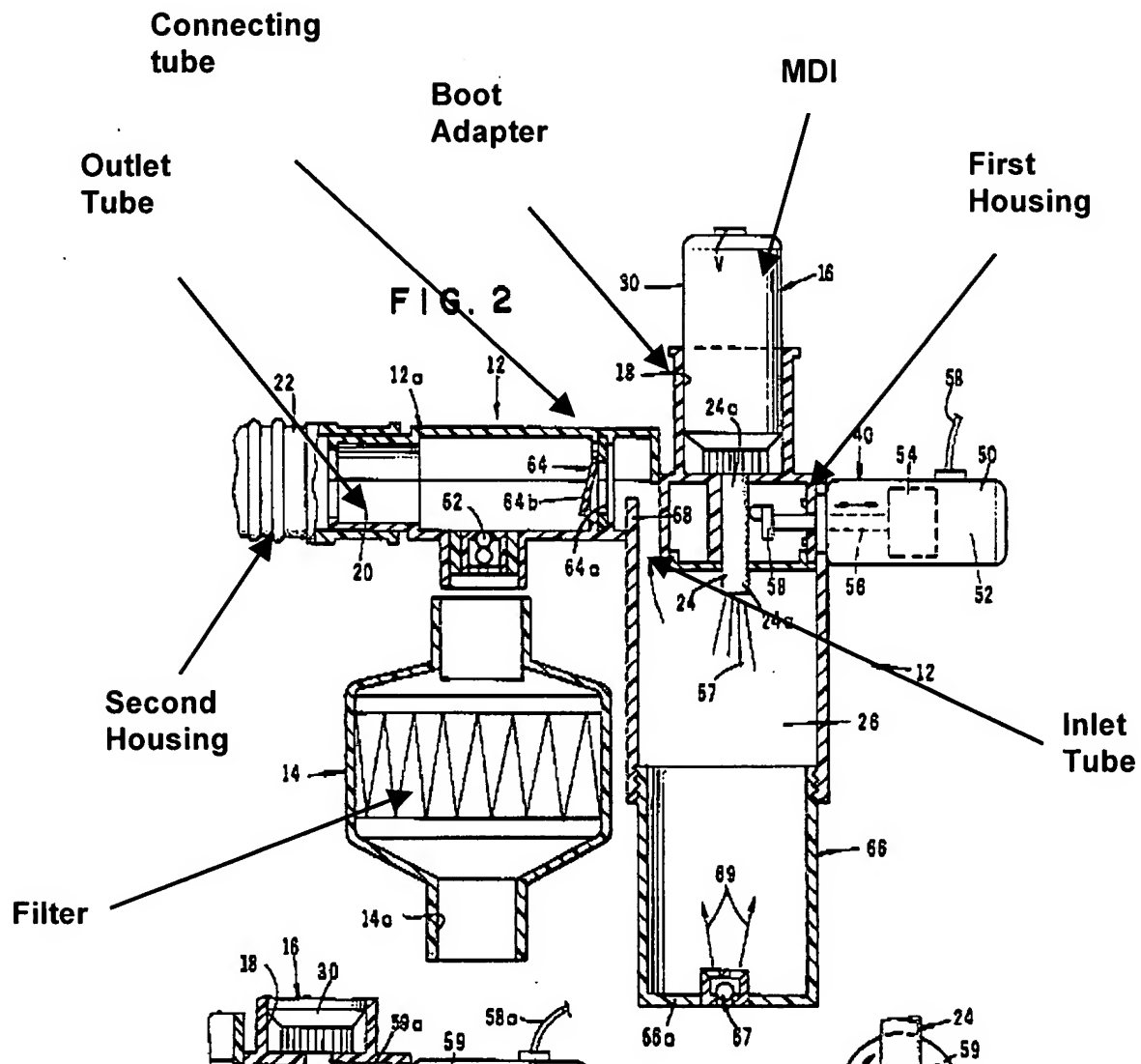
Regarding claim 5, King discloses a universal MDI adapter (at 68) that may be located at the inlet end of the central inlet tube of the first housing; the MDI adapter that may be used for delivering aerosol medication by actuation of MDI into the first housing (Figs. 2, 4); a nebulizer (at 16) that may generate aerosol medication in the second housing (Figs. 2, 4); the first housing and the second housing are connected at a central location by fusion of the outlet tube of the second housing to the inlet tube of the first housing, such as to form a passage to allow the aerosol medication to move between the two housings (Figs. 2, 4); the first housing and the second housing that **may** also be connected at peripheral locations by peripheral connecting tubes that are partially or fully collapsible/expandable such as to form a passage to allow the aerosol

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medication to move between the two housings (based upon the claim language that the housings may be connected at peripheral locations by peripheral connecting tubes that are partially or fully collapsible/expandable such as to form a passage to allow the aerosol medication to move between the two housings does not mean that they have to be and therefore King is readable upon the claim limitations).

Regarding claim 6, King discloses the device is useable with a facemask to deliver a desired mixture of gas(es), as to the desired density, viscosity, humidity, and fraction of inspired oxygen King does not specifically state such however, it would have been obvious to one of ordinary skill in the art in order for a user to be able to inhale the mixture of gas(es) the mixture would have to be the desired density, viscosity, humidity, and fraction of inspired oxygen.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show aerosol devices: 6,494,202; 5,865,172; 5,791,340.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Teena Mitchell

Primary Examiner

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September 13, 2007

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